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**VIA FEDERAL EXPRESS**

Food and Drug Administration  
555 Winderley Pl., Ste. 200  
Maitland, FL 32751

**WARNING LETTER**

FLA-01-72

July 25, 2001

**FACILITY ID # 223460**

William Arnold, Administrator  
Pasco Imaging and Open MRI Center  
7615 Jacque Road  
Hudson, Florida 34667

Dear Mr. Arnold:

We are writing to you because on June 29, 2001, your facility was inspected by a representative of the State of Florida acting in behalf of the Food and Drug Administration (FDA). This inspection revealed a serious regulatory problem involving the mammography at your facility. Under a United States Federal law, the Mammography Quality Standards Act of 1992, your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following findings at your facility:

**Level 1:**

Mammograms were processed in processor 1, AGFA-Gevaert, Mammoray MR, Darkroom, when it was out of limits for a minimum of five days.

**Level 2:**

Corrective actions for processor quality control failures were not documented at a minimum of one time for processor 1, AGFA-Gevaert, Mammoray MR, Darkroom.

Corrective action before further exams for a failing image score, or a phantom background optical density, or density difference outside the allowable regulatory limits, was not documented for unit 1, Lorad Medical Systems, Inc., MIII, Mammo room.

The specific problem noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection. Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, it represents a serious violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to \$10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the Standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

It is necessary for you to act on this matter immediately. Please explain to this office in writing within fifteen (15) working days from the date you received this letter:

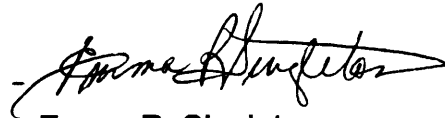
- the specific steps you have taken to correct all of the violations noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations;
- equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and
- sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records (Note: Patient names or identification should be deleted from any copies submitted).\*

Please submit your response to Timothy J. Couzins, Compliance Officer, U.S. Food & Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, (407) 475-4728.

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at <http://www.fda.gov>.

If you have more specific questions about mammography facility requirements, or the content of this letter, please feel free to contact D. Janneth Caycedo, Consumer Safety Officer, Boca Resident Post, U. S. Food and Drug Administration, 1499 West Palmetto Park Rd., Ste. 110, Boca Raton, Florida 33486 or at 561-338-5236, ext. 23.

Sincerely,

A handwritten signature in black ink, appearing to read "Emma R. Singleton", with a long horizontal flourish extending to the right.

Emma R. Singleton  
Director, Florida District